

MANNKIND CORP
Form 8-K
August 04, 2009

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 8-K
CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 4, 2009

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

000-50865

(Commission File Number)

13-3607736

(IRS Employer
Identification No.)

28903 North Avenue Paine

Valencia, California

(Address of principal executive offices)

91355

(Zip Code)

Registrant's telephone number, including area code: **(661) 775-5300**

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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In this Report, the Company, we, us and our refer to MannKind Corporation.

Item 8.01 Other Events.

We are filing the following information with the Securities and Exchange Commission for the purpose of updating certain aspects of our publicly disclosed descriptions of our business and outstanding shares.

OUR BUSINESS

MannKind Corporation is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Our lead product candidate is an ultra rapid-acting insulin known as AFRESA, which is also the trade name for the product that we have proposed to the United States Food and Drug Administration, or FDA. In March 2009, we submitted a new drug application, or NDA, to the FDA requesting approval of AFRESA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. The FDA accepted our NDA for filing in May 2009. We believe that the performance characteristics, unique kinetics, convenience and ease of use of AFRESA have the potential to change the way diabetes is treated.

We believe that a distinguishing characteristic of AFRESA is that it produces a profile of insulin levels in the bloodstream that approximates the insulin profile normally seen in healthy individuals immediately following the beginning of a meal, but which is absent in patients with diabetes. Specifically, AFRESA is rapidly absorbed into the bloodstream following inhalation, reaching peak levels within 12 to 14 minutes. As a result of this rapid absorption, most of the glucose-lowering activity of AFRESA occurs within the first three hours of administration which is generally when glucose becomes available from a meal instead of the much longer duration of action observed when insulin is injected subcutaneously. We believe that the relatively short duration of action of AFRESA reduces the need for patients to snack between meals in order to manage ongoing blood glucose excursions. In our clinical trials, we have observed that patients using AFRESA have achieved significant reductions in post-meal glucose excursions and significant improvements in overall glucose control, as measured by decreases in glycosylated hemoglobin, or A1C, levels, without the weight gain typically associated with insulin therapy.

We have conducted an extensive clinical program, involving more than 40 different studies of AFRESA. Approximately 5,300 subjects participated in our clinical studies, of which more than 2,900 subjects were administered AFRESA. These studies were conducted in healthy volunteers, patients with type 1 and type 2 diabetes as well as diabetic patients with renal dysfunction, liver dysfunction, chronic obstructive pulmonary disease, asthma and upper respiratory tract infections. In addition, we have completed construction and achieved operational readiness of our production facility in Danbury, Connecticut. We believe that our facility will satisfy the initial commercial demand for AFRESA. The facility also includes expansion space that will allow production capacity to be increased based on anticipated needs during the initial years of commercialization. We are preparing for pre-approval inspection of the facility by the FDA. We will only be able to market AFRESA in the United States once, and if, the FDA approves our application.

AFRESA utilizes our proprietary Technosphere formulation technology, which is based on a class of organic molecules that are designed to self-assemble into small particles onto which drug molecules can be loaded. Technosphere technology is not limited to insulin delivery. We believe it represents a versatile drug delivery platform that may allow pulmonary administration of certain drugs that currently require administration by injection. Beyond convenience, we believe the key advantage of drugs inhaled as Technosphere formulations is that they have been shown to be absorbed very rapidly into the arterial circulation.

We are also developing therapies for the treatment of different types of cancer, which do not utilize our Technosphere platform. We are currently completing two clinical trials of our therapeutic cancer vaccines. We expect to announce the results of these trials by the end of 2009.

OUTSTANDING SHARES

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As of June 30, 2009, the number of shares of our common stock outstanding was 103,646,376. This outstanding share number does not include, as of June 30, 2009:

5,476,258 shares of common stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$7.06 per share;

3,595,482 shares of common stock issuable upon the settlement of outstanding restricted stock units;

5,117,523 shares of common stock issuable upon the conversion of our outstanding 3.75% senior convertible notes due 2013 at a conversion price of approximately \$22.47 per share;

2,882,873 shares of common stock reserved for issuance upon the exercise of outstanding warrants with a weighted average exercise price of \$12.23 per share; and

9,487,966 shares of common stock available for future grant under our 2004 equity incentive plan, 2004 non-employee directors' stock option plan and 2004 employee stock purchase plan.

Forward-Looking Statements

Certain statements in this Report are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include, but are not limited to, statements about: the potential for AFRESA, the progress or success of our research, development and clinical programs for AFRESA, the timing or success of the commercialization of AFRESA, our ability to market, commercialize and achieve market acceptance for AFRESA, the adequacy of our production facility, the demand for AFRESA, our expected announcement of clinical trial results, our estimates for future performance, scientific studies and the conclusions we draw from them and our pending public offering of common stock. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, goal, intends, may, plans, potential, predicts, would, and similar expressions intended to identify forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from our expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to, risks related to the progress, timing and results of clinical trials, difficulties or delays in seeking or obtaining regulatory approval, the manufacture of AFRESA, competition from other pharmaceutical or biotechnology companies, MannKind's ability to enter into any collaborations or strategic partnerships, intellectual property matters, stock price volatility, inherent in attempting to engage in a public offering of common stock, particularly in the current market environment, and other risks. Additional factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements are disclosed in our filings with the Securities and Exchange Commission. These forward-looking statements represent our judgment as of the time of this report. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MANNKIND CORPORATION

By: /s/ David Thomson

Name: David Thomson, Ph.D., J.D.

Title: Corporate Vice President, General
Counsel and Secretary

Dated: August 4, 2009